Module 8 Assignment

585.751.81 Immunoengineering

1. Your boss wants to develop a new food allergy diagnostic and thinks that a new biomarker will work better than looking at IgE levels and skin prick test. What can you tell your boss about what the diagnostic development process will look like? (this can look like an informal email – and can use bullet points) Include in your answer: (30 points)

* Who needs to be involved in ideation
* How it needs to be tested and validated
* Target sensitivity and specificity
* Available technologies, market, and cost
* Source of sample and basic biology of a few potential targets
* Total time required

1. How might the microbiota be used both as a diagnostic and therapeutic agent in autoimmunity? Why is this an attractive approach? What are limitations with using the microbiota as a diagnostic or therapeutic agent? (15 points)
2. Compare and contrast cell engineering bacteria versus mammalian cell lines for therapeutic approaches. Also, give specific examples where you would use one versus the other. Finally, describe challenges for entry to market for these technologies. (15 points)
3. a) Design a combination therapy that uses **both** biomaterials **and** a biologic-based therapeutics to treat one of the following allergic or autoimmune diseases: (40 points)

* Asthma
* Seasonal allergies
* Multiple sclerosis
* Rheumatoid arthritis
* Chron’s disease

In consideration of your design, specify your design constraints used such as:

1. Cost
2. Manufacturing
3. FDA regulations
4. Biophysical properties – such as size, shape, stiffness, etc.
5. Definition of success, such as a comparison to gold standard or acceptable side effects
6. Whether it is inspired by nature or biological mechanisms

b) Finally, compare and contrast the biomaterial and biologic design processes with the experience of this and last week’s exercises.